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Mitsubishi Tanabe Pharma Corp.,
Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV,
Janssen Research and Development, LLC,
and Cilag GmbH International

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

MITSUBISHI TANABE PHARMA
CORPORATION, JANSSEN
PHARMACEUTICALS, INC., JANSSEN
PHARMACEUTICA NV, JANSSEN
RESEARCH AND DEVELOPMENT, LLC, and
CILAG GMBH INTERNATIONAL,

Plaintiffs,

v.

MACLEODS PHARMACEUTICALS, LTD., and
MACLEODS PHARMA USA, INC.,

Defendants.

Civil Action No. _____

**COMPLAINT FOR PATENT
INFRINGEMENT**

(Filed Electronically)

Plaintiffs Mitsubishi Tanabe Pharma Corp. (“MTPC”), Janssen Pharmaceuticals, Inc. (“JPI”), Janssen Pharmaceutica NV (“JNV”), Janssen Research and Development, LLC (“JRD”), and Cilag GmbH International (“Cilag”) (collectively, “Plaintiffs”), by their attorneys, for their complaint against Macleods Pharmaceuticals, Ltd. (“Macleods India”) and Macleods Pharma USA, Inc. (“Macleods USA”) (collectively, “Macleods”) allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 7,943,582 (the “’582 patent”) and 8,513,202 (the “’202 patent”) (collectively, the “Patents-in-suit”) under the patent laws of the United States, 35 U.S.C. §100, *et seq.* This action arises from Macleods India’s filing of Abbreviated New Drug Application (“ANDA”) No. 210783 (“the Macleods ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market generic versions of JPI’s 100 mg and 300 mg INVOKANA[®] drug product (“the Macleods ANDA Product”) prior to the expiration of the Patents-in-suit.

THE PARTIES

2. MTPC is a corporation organized and existing under the laws of Japan, having an office and place of business at 3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan.

3. JPI is a corporation organized and existing under the laws of the State of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. JNV is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, 2340 Beerse, Belgium.

5. JRD is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 920 Route 202, Raritan, New Jersey 08869.

6. Cilag is a company organized and existing under the laws of Switzerland, having its principal place of business at Gubelstrasse 34, 6300, Zug, Switzerland.

7. On information and belief, defendant Macleods India is a corporation organized and existing under the laws of India, having its principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, 40059, India.

8. On information and belief, defendant Macleods USA is a corporation organized under the laws of the State of Delaware, having its principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536.

THE PATENTS-IN-SUIT

9. On May 17, 2011, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’582 patent, entitled, “Crystalline form of 1-(β -D-glucopyransoyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate” to MTPC as assignee of inventors Sumihiro Nomura and Eiji Kawanishi. A copy of the ’582 patent is attached as Exhibit A.

10. JPI, JRD, and Cilag are exclusive licensees of the ’582 patent.

11. JNV is an exclusive sublicensee of the ’582 patent.

12. On August 20, 2013, the USPTO duly and lawfully issued the ’202 patent entitled, “Crystalline form of 1-(β -D-glucopyransoyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate” to MTPC as assignee of inventors Sumihiro Nomura and Eiji Kawanishi. A copy of the ’202 patent is attached as Exhibit B.

13. JPI, JRD, and Cilag are exclusive licensees of the ’202 patent.

14. JNV is an exclusive sublicensee of the ’202 patent.

THE INVOKANA[®] DRUG PRODUCT

15. JPI holds approved New Drug Application (“NDA”) No. 204042 for canagliflozin tablets, which are prescribed and sold under the trademark INVOKANA[®]. INVOKANA[®] is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

16. The claims of the Patents-in-suit cover, *inter alia*, certain polymorphic forms of canagliflozin.

17. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ’582 and ’202 patents are listed in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to INVOKANA[®].

JURISDICTION AND VENUE

18. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

19. This Court has personal jurisdiction over Macleods India because, *inter alia*, Macleods India has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of the Macleods ANDA, Macleods India will make, use, offer for sale, sell, and/or import the Macleods ANDA Product in the United States, including in New Jersey, prior to the expiration of the Patents-in-suit.

20. This Court also has personal jurisdiction over Macleods India because, *inter alia*, this action arises from actions of Macleods India directed toward New Jersey. For example, Macleods’s counsel sent a letter dated November 4, 2017 to JPI, a corporation with its

principal place of business in this Judicial District stating that Macleods had submitted ANDA No. 210783 seeking approval to commercially manufacture, use, import, offer for sale, and sell the Macleods ANDA Product prior to the expiration of the Patents-in-suit. If Macleods succeeds in obtaining FDA approval, it would sell its Macleods ANDA Product in New Jersey and other states, causing injury to Plaintiffs in New Jersey.

21. This Court also has personal jurisdiction over Macleods India because Macleods India has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Macleods India regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Macleods India derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. For example, Macleods India's website states that "Macleods has received FDA approval on 9 [ANDAs] and has another 60 filed and awaiting approval." Macleods US, <http://www.macleodspharma.com/UnitedStates.asp> (last visited December 14, 2017).

22. On information and belief, Macleods India has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey, and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

23. On information and belief, Macleods India derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

24. On information and belief, Macleods India has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases.

25. Macleods India has previously been sued in this Judicial District and has availed itself of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey, including *AstraZeneca AB, et al. v. Macleods Pharmaceuticals Ltd., et al.*, Civil Action No. 16-1682 (consenting to personal jurisdiction and venue for the purposes of the action and asserting counterclaims) and *Otsuka Pharmaceutical Co., Ltd. v. Macleods Pharmaceuticals Ltd., et al.*, Civil Action No. 15-5109 (consenting to personal jurisdiction and venue for the purposes of the action and asserting counterclaims).

26. On information and belief, Macleods India and its subsidiaries operate as a single, integrated generic pharmaceutical manufacturer. For example, on Macleods India's website, Macleods USA is described as "the U.S. division of Macleods Pharmaceuticals, LTD, a developer and manufacturer of Generic Active Pharmaceutical Ingredients (API) and Finished Dosage Forms." Macleods US, www.macleodspharma.com/UnitedStates.asp (last visited December 15, 2017).

27. On information and belief, Macleods USA is a wholly owned subsidiary of Macleods India and is controlled and dominated by Macleods India. Macleods US, <http://www.macleodspharma.com/UnitedStates.asp> (last visited December 15, 2017) ("Macleods Pharma USA is the U.S. division of Macleods Pharmaceuticals, LTD."). On information and belief, Macleods India is a "truly . . . global pharmaceutical company." Macleods, <http://www.macleodspharma.com/default.asp> (last visited December 15, 2017). On information

and belief, Macleods India is “a vertically integrated global pharmaceutical company” with “more than 10,000 professionally qualified employees across the globe.” *Id.*

28. On information and belief, Macleods USA is in the business of, *inter alia*, developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District. Macleods US, www.macleodspharma.com/UnitedStates.asp (last visited December 15, 2017) (“Macleods Pharma USA is the U.S. division of Macleods Pharmaceuticals, LTD, a developer and manufacturer of Generic Active Pharmaceutical Ingredients (API) and Finished Dosage Forms.”). On information and belief, Macleods USA markets, distributes, sells, and/or offers for sale generic drugs throughout the United States and in New Jersey at the direction of, under the control of, and for the direct benefit of Macleods India. On information and belief, Macleods USA “is based in Plainsboro, NJ.” *Id.* This Court has jurisdiction over Macleods India because, on information and belief, Macleods India is the parent corporation of Macleods USA.

29. In the alternative, this Court has jurisdiction over Macleods India because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs’ claims arise under federal law; (b) Macleods India is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Macleods India has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court’s exercise of jurisdiction over Macleods India satisfies due process.

30. Venue is proper for Macleods India under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia*, Macleods India is a foreign corporation and is subject to personal jurisdiction in this Judicial District, as set forth above. In addition, Macleods India has committed an act of infringement and will commit further acts of infringement in this Judicial District, as set forth in paragraphs 19-20 above, continuously transacts business in this Judicial District, as set forth in paragraph 21 above, and has a continuous and permanent presence in this Judicial District through its subsidiary, Macleods USA.

31. This Court has personal jurisdiction over Macleods USA because, *inter alia*, Macleods USA intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of the Macleods ANDA, Macleods USA will work in concert with Macleods India to make, use, offer for sale, sell, and/or import the Macleods ANDA Product in the United States, including in New Jersey, prior to the expiration of the Patents-in-suit. On information and belief, Macleods USA is registered as a wholesaler in the State of New Jersey (No. 5004370). *See New Jersey Registration and Verification*, <http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx> (last visited December 15, 2017).

32. This Court also has personal jurisdiction over Macleods USA because, *inter alia*, this action arises from actions of Macleods USA directed toward New Jersey, and because Macleods USA has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Macleods USA maintains its principal place of business in New Jersey and regularly and continuously transacts business within New Jersey, including by selling

pharmaceutical products in New Jersey. On information and belief, Macleods USA derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. On information and belief, Macleods USA is registered as a wholesaler in the State of New Jersey (No. 5004370). See New Jersey Registration and Verification, <http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx> (last visited December 15, 2017).

33. On information and belief, Macleods USA has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey, and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

34. On information and belief, Macleods USA derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

35. On information and belief, Macleods USA has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases.

36. Macleods USA has previously been sued in this Judicial District and has availed itself of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey, including *AstraZeneca AB, et al. v. Macleods Pharmaceuticals Ltd., et al.*, Civil Action No. 16-1682 (consenting to personal jurisdiction and venue for the purposes of the action and asserting counterclaims) and *Otsuka Pharmaceutical Co., Ltd. v. Macleods Pharmaceuticals Ltd., et al.*, Civil Action No. 15-5109 (consenting to personal jurisdiction and venue for the purposes of the action and asserting counterclaims).

37. Venue is proper for Macleods USA under 28 U.S.C. § 1400(b) because, *inter alia*, Macleods USA has a regular and established place of business in New Jersey and will commit further acts of infringement in this Judicial District, as set forth in paragraphs 31-32 above.

MACLEODS INDIA’S INFRINGING ANDA SUBMISSION

38. On or about November 6, 2017, JPI received from Macleods India’s counsel a letter, dated November 4, 2017 (“Macleods November 4 Letter”), stating that Macleods India had submitted the Macleods ANDA to the FDA seeking approval to market the Macleods ANDA Product before the expiration of the Patents-in-suit. MTPC received the Macleods November 4 Letter on or about November 7, 2017.

39. Macleods India specifically directed the Macleods November 4 Letter to JPI’s headquarters in Titusville, New Jersey, within this Judicial District.

40. The Macleods ANDA Product is intended to be a generic version of INVOKANA[®].

41. On information and belief, following FDA approval of Macleod’s ANDA, Macleods India and Macleods USA will work in concert with one another to make, use, offer to sell, or sell the Macleods ANDA Product throughout the United States, or import such generic products into the United States.

42. The Macleods November 4 Letter alleges that the Macleods ANDA Product does not infringe the ’582 patent or the ’202 patent. Notwithstanding these allegations, on information and belief, discovery/testing will show that the Macleods ANDA Product infringes the Patents-in-suit.

43. This action is being commenced before the expiration of 45 days from the date MTPC and JPI received the Macleods November 4 Letter.

COUNT I

Infringement of U.S. Patent No. 7,943,582 by Macleods India and Macleods USA

44. Plaintiffs repeat and reallege paragraphs 1-43 above as if fully set forth herein.

45. By filing its ANDA No. 210783 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Macleods ANDA Product before the expiration of the '582 patent, Macleods India committed an act of infringement under 35 U.S.C. § 271(e)(2).

46. On information and belief, discovery/testing will show that if Macleods India and/or Macleods USA commercially makes, uses, offers to sell, or sells the Macleods ANDA Product within the United States, or imports the Macleods ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '582 patent, it would further infringe at least claims 1, 6, and 7 of the '582 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

47. Macleods India has had knowledge of the '582 patent since at least the date Macleods India submitted the Macleods ANDA. Macleods USA has had knowledge of the '582 patent since at least October 4, 2017, when it was served with the complaint in *Mitsubishi Tanabe Pharma Corp., et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 17-5005 (PGS)(DEA).

48. Plaintiffs will be irreparably harmed if Macleods India and Macleods USA are not enjoined from infringing the '582 patent. Plaintiffs do not have an adequate remedy at law.

COUNT II

Infringement of U.S. Patent No. 8,513,202 by Macleods India and Macleods USA

49. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

50. By filing its ANDA No. 210783 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Macleods ANDA Product before the expiration of the '202 patent, Macleods India committed an act of infringement under 35 U.S.C. § 271(e)(2).

51. On information and belief, discovery/testing will show that if Macleods India and/or Macleods USA commercially makes, uses, offers to sell, or sells the Macleods ANDA Product within the United States, or imports the Macleods ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '202 patent, it would further infringe at least claims 1 and 3-5 of the '202 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

52. Macleods India has had knowledge of the '202 patent since at least the date Macleods India submitted the Macleods ANDA. Macleods USA has had knowledge of the '582 patent since at least October 4, 2017, when it was served with the complaint in *Mitsubishi Tanabe Pharma Corp., et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 17-5005 (PGS)(DEA).

53. Plaintiffs will be irreparably harmed if Macleods India and Macleods USA are not enjoined from infringing the '202 patent. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Macleods India has infringed one or more claims of the '582 patent by filing ANDA No. 210783;

B. Judgment that Macleods India and Macleods USA have infringed, and that Macleods India's and/or Macleods USA's making, using, offering to sell, selling, or importing the Macleods ANDA Product would constitute infringement of one or more claims of the '582 patent, and/or induce or contribute to the infringement of one or more claims of the '582 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

C. A permanent injunction restraining and enjoining Macleods India and Macleods USA, and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Macleods ANDA Product until after the expiration of the '582 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. An Order that the effective date of any approval of ANDA No. 210783 relating to the Macleods ANDA Product be a date that is not earlier than the expiration date of the '582 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

E. A Judgment that Macleods India has infringed one or more claims of the '202 patent by filing ANDA No. 210783;

F. A Judgment that Macleods India and Macleods USA have infringed, and that Macleods India's and/or Macleods USA's making, using, offering to sell, selling, or importing the Macleods ANDA Product would constitute infringement of one or more claims of

the '202 patent, and/or induce or contribute to the infringement of one or more claims of the '202 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

G. A permanent injunction restraining and enjoining Macleods India and Macleods USA, and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Macleods ANDA Product until after the expiration of the '202 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

H. An Order that the effective date of any approval of ANDA No. 210783 relating to the Macleods ANDA Product be a date that is not earlier than the expiration date of the '202 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled; and

I. Such other and further relief as the Court may deem just and proper.

Dated: December 15, 2017

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Pharmaceutica NV, Janssen Research
and Development, LLC, and Cilag
GmbH International

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that the matters captioned *Mitsubishi Tanabe Pharma Corporation, et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 17-5005 (PGS)(DEA), *Mitsubishi Tanabe Pharma Corporation, et al. v. Princeton Pharmaceutical Inc., et al.*, Civil Action No. 17-5135 (PGS)(DEA), *Mitsubishi Tanabe Pharma Corporation, et al. v. Apotex, Inc., et al.*, Civil Action No. 17-5278 (PGS)(DEA), *Mitsubishi Tanabe Pharma Corporation, et al. v. MSN Laboratories Private Ltd., et al.*, Civil Action No. 17-5302 (PGS)(DEA), and *Mitsubishi Tanabe Pharma Corporation, et al. v. Princeton Pharmaceuticals, Inc.*, Civil Action No. 17-7342 (FLW)(DEA) are related to the matter in controversy because the matter in controversy involves one of the same patents. I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding

Dated: December 15, 2017

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